

MECLIZINE HYDROCHLORIDE- meclizine hydrochloride tablet, chewable DIRECT RX

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

MECLIZINE HYDROCHLORIDE

Active ingredient (in each chewable tablet)

Meclizine HCl 25 mg

Purpose

Antiemetic

prevents and treats nausea, vomiting or dizziness due to motion sickness

Do not use in

children under 12 years of age unless directed by a doctor

Ask a doctor before use if you have

- ☐ glaucoma
- ☐ a breathing problem such as emphysema or chronic bronchitis
- ☐ trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if

you are taking sedatives or tranquilizers

When using this product

- ☐ Do not exceed recommended dosage
- ☐ may cause drowsiness
- ☐ alcohol, sedatives, and tranquilizers may increase drowsiness
- ☐ avoid alcoholic drinks
- ☐ use caution when driving a motor vehicle or operating machinery

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

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□ Dosage should be taken one hour before travel starts

adults and children 12

years of age and over chew 1 to 2 tablets once daily, or as directed by a doctor

children under

12 years of age do not give this product to children under 12 years of age

unless directed by a doctor

□ Each tablet contains 0.09 mg of Magnesium and 0.82 mg of Sodium

□ store at room temperature in a dry place

□ keep lid tightly closed

Croscarmellose Sodium, Crospovidone, FD&C Red #40 Lake, French Vanilla Flavor, Lactose, Magnesium Stearate, Raspberry Flavor, Silica, Sodium Saccharin, Stearic Acid

1-800-645-2158

THIS PACKAGE FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

*This product is not manufactured or distributed by Prestige Brands, Inc owner of the registered trademark Bonine®.

Distributed by:

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www.rugbylaboratories.com



MECLIZINE HYDROCHLORIDE

meclizine hydrochloride tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72189-196(NDC:0536-1299)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MECLIZINE HYDROCHLORIDE (UNII: HDP7W44CIO) (MECLIZINE - UNII:3L5TQ84570)	MECLIZINE HYDROCHLORIDE	25 mg

Inactive Ingredients

Ingredient Name	Strength
STEARIC ACID (UNII: 4ELV7Z65AP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSPVIDONE, UNSPECIFIED (UNII: 2S7830E561)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
RASPBERRY (UNII: 4N14V5R27W)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
VANILLA (UNII: Q74T35078H)	

Product Characteristics

Color	pink	Score	2 pieces
Shape	ROUND	Size	9mm
Flavor	RASPBERRY, VANILLA	Imprint Code	5172
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72189-196-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	04/12/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part336	04/12/2021	

Labeler - DIRECT RX (079254320)

Registrant - DIRECT RX (079254320)

Establishment

Name	Address	ID/FEI	Business Operations
DIRECT RX		079254320	repack(72189-196)

Revised: 4/2021

DIRECT RX